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(21) International Application Number: PCT/US99/13509 (22) International Filing Date: 16 June 1999 (16.06.99) (30) Priority Data: 09/098,606 17 June 1998 (17.06.98) US (71) Applicant: SURGICAL DYNAMICS, INC. [US/US]; 111 Glover Avenue, Norwalk, CT 06856 (US). (72) Inventor: MIDDLETON, Lance; 490 Booth Hill Road, Trum- bull, CT 06611 (US). (74) Agent: GERSHON, Neil, D.; United States Surgical Corpora- tion, 150 Glover Avenue, Norwalk, CT 06856 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: ARTIFICIAL INTERVERTEBRAL DISC (57) Abstract An intervertebral prosthesis includes a disc member dimensioned for insertion within an intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom. The disc member has sufficient rigidity to support the adjacent vertebrae in spaced relation, and defines a longitudinal axis extending the height of the disc member and a lateral axis transverse to the longitudinal axis. The disc member includes an exterior wall which has a slit defined therein. The slit defines a longitudinal component of direction and a lateral component of direction. Preferably, the exterior wall includes a plurality of helical slits, adjacent slits being disposed in at least partial overlapping relation to define an overlapping region. Upon insertion of the disc member within the intervertebral space with the support surfaces in contacting engagement with respective vertebral portions of the adjacent vertebrae, forces exerted by the vertebral portions on the support surfaces are transferred along the exterior wall through the overlapping region.		

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ARTIFICIAL INTERVERTEBRAL DISC

5

BACKGROUND

1. Field of the Disclosure

10 The present disclosure generally relates to apparatus and techniques for treatment of spinal disorders, and, in particular, relates to an artificial intervertebral prosthesis which restores both the height and shape of the intervertebral disc space following the removal of a damaged or diseased intervertebral disc while maintaining the natural biomechanics of the spinal motion segment.

2. Description of the Prior Art

15 The objective in invertebral disc replacement is to provide a prosthetic disc that combines both stability to support the high loads of the patient's vertebrae and flexibility to provide the patient with sufficient mobility and proper spinal column load distribution. In attempting to strike this balance, generally, four basic types of artificial intervertebral discs for replacing a part or all of a removed disc have been developed,
20 namely, elastomer discs, ball and socket discs, mechanical spring discs and hybrid discs. Elastomer discs typically include an elastomer cushion which is sandwiched between lower and upper rigid endplates. The elastomer discs are advantageous in that the elastomer cushion functions similar in mechanical behavior to the removed intervertebral disc tissue. However, a disadvantage of this disc type is that the
25 elastomer cushion experiences long term in-vivo problems stemming from microcracking, which detracts from its usefulness as a replacement option. Furthermore, attachment of the flexible elastomer cushion to rigid endplates presents additional difficulties. Examples of elastomer discs are disclosed in U.S. Patent Nos. 5,702,450 to Bissarie; 5,035,716 to Downey; 4,874,389 to Downey; and 4,863,477 to
30 Monson.

-2-

Ball and socket discs typically incorporate two plate members having cooperating inner ball and socket portions which permit articulating motion of the members during movement of the spine. The ball and socket arrangement is adept in restoring "motion" of the spine, but, is poor in replicating the natural stiffness of the intervertebral disc. Dislocation and wear are other concerns with this disc type. Examples of ball and socket discs are disclosed in U.S. Patent Nos.: 5,507,816 to Bullivant and 5,258,031 to Salib et al.

Mechanical spring discs usually incorporate one or more coiled springs disposed between metal endplates. The coiled springs preferably define a cumulative spring constant sufficient to maintain the spaced arrangement of the adjacent vertebrae and to allow normal movement of the vertebrae during flexion and extension of the spring in any direction. Disadvantages of the mechanical spring disc types involve attachment of the coiled springs to the metal end plates and associated wear at the attachment points. Examples of mechanical spring discs are disclosed in U.S. Patent Nos. 5,458,642 to Beer et al. and 4,309,777 to Patil.

The fourth type of artificial intervertebral disc, namely, the hybrid type incorporates two or more principles of any of the aforescribed disc types. For example, one known hybrid disc arrangement includes a ball and socket set surrounded by an elastomer ring. This hybrid disc provides several advantages with respect to load carrying ability, but, is generally complex requiring a number of individual components. Furthermore, long term in vivo difficulties with the elastomer cushion remain a concern as well as wear of the ball and socket arrangement.

Another type of intervertebral disc prosthesis is disclosed in U.S. Patent No. 5,320,644 to Baumgartner. With reference to FIGS. 1-3, the Baumgartner '644 device is a unitary intervertebral disc member 1 made from a strong, elastically deformable material. The disc member 1 has parallel slits 5 each arranged at a right angle to the axis of the disc member. The parallel slits 5 partially overlap one another to define overlapping regions 6 between adjacent slits. The overlapping regions 6 create leaf springs 7 for the transmission of forces from one vertebral attachment

-3-

surface to the other. In regions of adjacent slits 5 where they do not overlap the spring action on the leaf springs 7 is interrupted by fixation zones 9 of solid prosthesis material. The forces acting on the intervertebral disc are transmitted from one leaf spring plane to the next leaf spring plane via the fixation zones 9.

5 However, the load paths are inherently abrupt with highly localized transfer of load through the sparsely placed fixation zones 9. There are even instances where the entire load is carried through a single fixation zone 9 in the center of the disc. The abrupt load paths can lead to high stress regions, which can detract from the appropriate biomechanical performance, i.e., strength, flexibility, and range-of-motion,
10 of the prosthesis.

 The need therefore exists for a prosthetic disc which is easy to manufacture and provides the proper balance of flexibility and stability through improved load distribution.

15 SUMMARY

 Accordingly, the present disclosure is directed to an intervertebral disc prosthesis for insertion within the intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom. The intervertebral prosthesis includes a disc member having a longitudinal axis extending
20 the height of the disc member and a radial axis transverse to the longitudinal axis. The disc member includes an external wall having at least one slit therein. The at least one slit has a first component of direction and a second different component of direction and facilitates transfer of load along the exterior wall.

 Preferably, the exterior wall includes a plurality of helical slits, adjacent
25 slits being disposed in radial relation with respect to the longitudinal axis whereby load transfer occurs along the exterior wall. The slits give the exterior wall flexibility consistent with the natural intervertebral disc.

 The disc member may further include an inner cavity. Preferably, the slit(s) extends from an outer wall surface of the exterior wall to an inner wall surface

-4-

thereof in communication with the inner cavity. First and second longitudinally opposed support surfaces are disposed at the longitudinal ends of the disc. The support surfaces are dimensioned to supportingly engage vertebral portions of respective vertebrae. At least one of the first and second support surfaces has an opening
5 extending therethrough in communication with the inner cavity.

An end cap may be releasably mounted to the support surfaces and at least partially positionable within the opening in the support surface. The end cap may include an inner opening dimensioned to reduce rigidity thereof.

10 **BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

FIGS. 1-3 illustrate a prior art intervertebral disc prosthesis;

FIG. 4 is a perspective view of the artificial intervertebral prosthesis in
15 accordance with the principles of the present disclosure, including the disc member and the end cap(s) mounted to the disc member;

FIG. 5 is a perspective view of the intervertebral prosthesis of FIG. 4 with the end caps removed from the disc member;

FIG. 6 is a cross-sectional view of the intervertebral prosthesis of FIG. 4;

20 FIG. 7 is a view illustrating a portion of the vertebral column;

FIG. 8 is a view taken along the lines 8-8 of FIG. 7 illustrating the intervertebral prosthesis of FIG. 4 positioned within the intervertebral space defined between adjacent vertebrae;

FIG. 9 is a perspective view of an alternate embodiment of the
25 intervertebral disc prosthesis;

FIG. 10 is a perspective view of another alternate embodiment of the intervertebral disc prosthesis;

FIG. 11A is a cross-sectional view taken through the vertebral body to illustrate a top view of the fusion cage of the present disclosure; and

FIG. 11B is a perspective view of the fusion cage of FIG. 11A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, in which like reference numerals identify
5 similar or identical elements throughout the several views, and referring in particular to
FIGS. 4-6, the artificial intervertebral prosthesis of the present disclosure is illustrated.
Intervertebral prosthesis 100 is intended to replace part or all of the supporting function
of a diseased intervertebral disc which had been previously removed through a
discectomy procedure or the like. Intervertebral prosthesis 100 is advantageously
10 dimensioned to be positioned between adjacent vertebrae in supporting contacting
relation with the vertebral end plates thereof to maintain the adjacent vertebrae in
appropriate spaced relation while restoring the natural biomechanics (e.g., including
stiffness, range of motion, and strength) of the spinal or vertebral segment.

Intervertebral prosthesis 100 includes two basic components, namely,
15 disc or body member 102 and first and second end-caps 104, 106 which are releasably
mounted to the body member 102. Body member 102 is in the general shape of an
intervertebral disc (e.g., kidney-shaped) as shown and defines longitudinal axis "a"
extending along the height of the member 102 and radial axis "b" generally transverse
to the longitudinal axis "a". An angular reference is defined by "c" as shown. (FIG.
20 5) Body member 102 includes first and second longitudinally opposed (e.g., upper and
lower) support surfaces 108, 110 which supportingly engage the respective end faces of
the adjacent vertebrae upon insertion of the prosthesis, and exterior wall 112 extending
between the support surfaces 108, 110. Support surfaces 108, 110 are each arcuate in
configuration defining a slight outer curvature which preferably corresponds to the
25 slight inward curvature of the vertebral end plates so as to facilitate positioning and
retention of the prosthesis within the intervertebral space.

Body member 102 further includes a centrally located cannulation 116 in
general alignment with the longitudinal axis "a" and extending through support
members 108, 110. (FIG. 5) Cannulation or bore 116 defines an inner cavity 114 and

-6-

central openings 118 of the support surfaces 108, 110. In the embodiment illustrated in FIG. 4, openings 118 are correspondingly dimensioned to at least partially receive their respective end caps 104, 106. An enlarged circumferential recess 120 is defined within each support surface 108, 110 about the periphery of each opening 118 to receive the head portion 130 on the end caps 104, 106. As shown, the end caps 104, 106 once inserted, are generally flush with the upper and lower surfaces 114. The end caps 104, 106 provide additional surfaces 134 for bone attachment and prevent bone growth into the body member 102. The engagement surfaces 142, 144 of the end caps 104, 106, during high load contact each other and serve several purposes: (1) prevent the exterior walls 112 from being overstressed by providing an alternate load path (through the center of the disc); (2) increase the overall stiffness of disc 100 in a similar manner as the natural disc which becomes more rigid with high loads; and (3) prevent complete closure of the generally helical slits 122, reducing a "pinching" effect on surrounding soft tissue. Internal bore 138 with its associate slotted openings 140 effectively reduce the rigidity of the end caps 104, 106, so that the overall stiffness of the disc 100 will be more consistent with the natural intervertebral disc.

With continued reference to FIGS. 4-6, exterior wall 112 has a plurality of slits 122 defined therein which, in the preferred embodiment, extend completely through the exterior wall from its outer surface 124 to its inner surface 126 in communication with the inner cavity 114. (FIG. 6) Each slit 122 is generally helical in configuration, i.e., each slit 122 has a longitudinal component of direction and an angular component of direction as shown. These different directional components e.g. a longitudinal and lateral direction, result in a multi-directional path for each of the slits 122. Slits 122 are preferably disposed about the exterior wall at predetermined spaced radial locations whereby adjacent longitudinal slits 122 are in partial overlapping arrangement. In the illustrated embodiment, five slits 122 are provided which are radially spaced at 72° intervals, although alternate numbers of slits and other spaced intervals are contemplated.

The slits 122 as shown extend about 180° around the exterior wall 112,

-7-

although they can extend less than or greater than 180° . A single generally helical slit may be used, however, the preferred embodiment provides a plurality of generally helical slits 122. The helical slits 122 are displaced in a radial relation with respect to the radial axis "b" and angle "c". The remaining load path 128 of the disc wall 112 has a spring-like characteristic, similar to a compressive or coiled spring. The plurality of load paths 128 create a flexible disc wall 112 and allow the transfer of loads between upper support surface 108 and lower support surface 110, in a continuous manner without abrupt load paths.

Although helical slits are shown, it is also contemplated that other multi-directional slits, i.e. having a lateral and longitudinal component of direction can be utilized. This can include slits that are smooth, piecewise smooth, open-looped, etc.

With further reference to FIGS. 4-6, end caps 104, 106 each define circumferential ledge or head portion 130 and main portion 132 of reduced dimension. End caps 104, 106 are at least partially received within central openings 118 of support surfaces 108, 110 in a manner whereby circumferential head portion 130 resides in correspondingly dimensioned circumferential recess 120 of the support surface 108, 110 and main portion 132 extends within the cannulation 116. The outer surface 134 of each end cap 104, 106 is preferably arcuate in shape generally corresponding to the arcuate configuration of the outer support surface 108, 110 to form a smooth transition from the outer support surfaces 108, 110 to the end cap. End caps 104, 106 each further include an indentation 136 defined in outer support surface 134 for attaching an instrument to releasably hold the end cap 104, 106 during insertion into the body member's 102 central openings 118. Indentation 136 is generally clover-shaped although other shapes are contemplated including rectangular, hexagonal, etc. to receive appropriate instrumentation. Main portion 132 of each end cap 104, 106 has a central internal bore or cavity 138 which extends through its outer wall to define a plurality (e.g., 4) of radially arranged slotted openings 140. Internal bore 138 with its associated radial openings 140 effectively reduce the rigidity of the respective end caps 104, 106. The caps can alternatively have helical slits instead of openings 140 to further reduce

-8-

stiffness.

The components of intervertebral prosthesis 100 are fabricated from a suitable rigid material including stainless steel, titanium or a suitable polymeric material. Preferably, the body member 102 is monolithically formed as a single unit although it is envisioned that in an alternate embodiment the body member 102 is composed of separate components, each of which would have the structural features, e.g. helical slit and inner cavity, discussed above. For example, three components can be utilized which when placed in juxtaposition in the intervertebral space form the kidney shape of FIG. 4.

Insertion of the Artificial Intervertebral Disc

With reference to FIGS. 7-8, the insertion of the artificial intervertebral disc will be discussed. The intervertebral space "i" defined between adjacent vertebrae "V₁, V₂" is accessed utilizing appropriate retractor instrumentation or the like.

Thereafter, a partial or full discectomy is performed to remove the diseased portion of the disc. The adjacent vertebrae "V₁, V₂" are distracted with appropriate distractor instrumentation to expose the intervertebral space. The artificial intervertebral prosthesis 100 is then positioned within the intervertebral space "i". Upon placement, the upper and lower support surfaces 108, 110 engage the respective vertebral end plates of the adjacent vertebrae in supporting relation therewith. As noted above, the arcuate contours defined by the outer surfaces 134 of the end caps 104, 106 and outer surfaces of the upper and lower support surfaces 108, 110 approximates the arcuate contour of the vertebral end plates to snugly fit within the adjacent vertebrae and facilitate retention within the intervertebral space.

As indicated hereinabove, the artificial intervertebral prosthesis 100 is characterized by having sufficient rigidity to maintain the adjacent vertebrae in spaced relation while possessing adequate flexibility to permit flexural movement of the vertebral column. The loads applied to the intervertebral prosthesis 100 are transmitted between the upper and lower support surfaces 108, 110 through the exterior wall 112

along generally continuous paths via the helical slit 122 arrangement and the resulting plurality of load paths 128.

Alternate Embodiment(s)

5 FIG. 9 illustrates an alternate embodiment of the present disclosure. Intervertebral prosthesis 200 includes disc or body member 202 which is substantially similar to body member 102 of the embodiment of FIG. 4. However, in accordance with this embodiment, end caps 104, 106 are eliminated such that the support surfaces 208, 210 are continuous. Also, there are no openings 118 within the support surfaces
10 as in the embodiment of FIG. 4 (see surfaces 108, 110). The cavity or bore (not shown) extends internally between surfaces 208, 210. Thus, in accordance with this embodiment, the prosthesis is a single monolithically formed unit. Prosthesis 200 can include internal "caps" which contact each other under heavy load to thereby function in a similar manner to the caps 104, 106 of prosthesis 100 of FIG. 4.

15 FIG. 10 illustrates another alternate embodiment of the present disclosure. Prosthesis 300 is substantially similar to prosthesis 100 of FIG. 4, however, in accordance with this embodiment, exterior wall 312 includes a single continuous helical slit 302 which extends from a position adjacent upper support surface 308 to a position adjacent lower support surface 310. The load paths are designated by reference
20 numeral 328. This provides more flexibility. Continuous slit 302 defines overlapping regions wherein longitudinally displaced portions of the continuous slit are in partial overlapping relation. These overlapping regions of the continuous slit 302 also provide for a continuous load transfer from upper support surface 108 to lower support surface 110, the benefits of such arrangements being discussed hereinabove. End caps 104 and
25 106 can optionally be provided.

-10-

Fusion Cage with Helical Slit(s)

The present disclosure also includes a unique fusion cage illustrated in FIGS. 11A and 11B and designated generally by reference numeral 500. In the use of spinal fusion cages, load sharing with the bone graft packed within the cage is necessary to transform the bone graft into a solid bony arthrodesis. With current fusion cages, such as those made of titanium alloy, the cage is rigid, resulting in the cage as the dominant load path during the fusion process.

The fusion cage 500 of the present disclosure is preferably composed of a titanium alloy. However, the cage includes a slit configuration to reduce stiffness. That is, the helical slits 522 provide the cage with additional flexibility so they flex under load, resulting in greater load sharing with the graft. As can be appreciated, fusion cage 500 has the identical helical slit configuration as the prosthetic disc of FIG. 4, and therefore the slit configuration will not be described again. Note that the slit design of FIG. 10 can also be utilized.

Cage 500 includes an internal cavity 502 to receive bone graft material "g" (see FIG. 11A). End caps (not shown) can be provided to help retain the bone graft material and to limit flexure as described above, as long as the caps have openings communicating with the internal cavity 502 to ensure contact between the bone graft material and vertebrae. Once the cage 500 is placed in the vertebral space "i" with support surfaces 508, 510 contacting the vertebrae, this bone graft material inside cavity 502 fuses with the adjacent vertebrae over time. As shown in FIG. 11A, as with current fusion cages, cage 500 is smaller than the overall disc space. Although one is shown, it is contemplated that two or more cages 500 can be placed side by side in the disc space.

Also, since fusion cage 500 does not fill the entire disc space, shapes other than the kidney shape of FIG. 11A and 11B are also contemplated, provided they contain the slit configuration to reduce overall flexibility

It will be understood that various modifications may be made to the embodiment disclosed herein. Therefore, the above description should not be construed

-11-

as limiting but merely as an exemplification of a preferred embodiment. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

-12-

WHAT IS CLAIMED IS:

1. An intervertebral prosthesis, which comprises a disc member dimensioned for insertion within an intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom, the disc member defining a longitudinal axis extending the height of the disc member and a radial axis transverse to the longitudinal axis, the disc member defining an exterior wall having at least one slit therein, the at least one slit defining a first component of direction and a second component of direction different from the first component of direction.
5
- 10 2. The intervertebral prosthesis according to claim 1 wherein the exterior wall includes a plurality of slits, adjacent slits being disposed in at least partial overlapping relation with respect to the longitudinal axis.
- 15 3. The intervertebral prosthesis according to claim 2 wherein at least portions of three slits are disposed in overlapping relation.
- 20 4. The intervertebral prosthesis according to claim 1, wherein the exterior wall includes a plurality of slits, adjacent slits being disposed in radial relation with respect to the longitudinal axis.
5. The intervertebral prosthesis according to claim 1, wherein the first direction defines a longitudinal component of direction and the second direction defines a lateral component of direction.
- 25 6. The intervertebral prosthesis according to claim 1, wherein the second direction defines an angular component of direction.

-13-

7. The intervertebral prosthesis according to claim 1 wherein the disc member includes first and second support surfaces disposed at respective longitudinal ends of the disc member and dimensioned to supportingly engage vertebral portions of respective vertebrae.

5

8. The intervertebral prosthesis according to claim 7, wherein the disc member includes a central opening extending through one or more of the support surfaces in communication with the inner cavity.

10

9. The intervertebral prosthesis according to claim 8 further including an end cap releasably mounted to the one support surface, the end cap positionable within the opening.

15

10. The intervertebral prosthesis according to claim 9 including first and second end caps releasably mounted to respective first and second support surfaces, the end caps positionable within respective openings of the first and second support surfaces.

20

11. The intervertebral prosthesis according to claim 9 wherein the end cap includes an inner opening dimensioned to minimize rigidity of the end cap.

25

12. The intervertebral prosthesis according to claim 2 wherein the disc member is monolithically formed having the first and second support surfaces formed therewith.

13. The intervertebral prosthesis according to claim 1 wherein the exterior wall includes a continuous slit therein, the slit arranged about the exterior wall such that longitudinally displaced portions of the slit are in at least partial overlapping relation.

-14-

14. The intervertebral prosthesis according to claim 1 wherein the disc member includes an inner cavity.

5 15. The intervertebral prosthesis according to claim 14 wherein the exterior wall defines an outer wall surface and an inner wall surface and wherein the slits each extend from the outer wall surface to the inner wall surface in communication with the inner cavity.

10 16. An intervertebral prosthesis, comprising a body member dimensioned for insertion within an intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom, the body member including an exterior wall, an inner cavity and support surfaces disposed at respective ends of the exterior wall, the exterior wall having a plurality of helical slits defined
15 therein and extending to communicate with the inner cavity.

17. An intervertebral prosthesis, according to claim 16 wherein the helical slits are positioned such that at least two adjacent helical slits are in partial overlapping relation to define an overlapping region.

20 18. The intervertebral prosthesis according to claim 17 wherein the helical slits are arranged such that at least three slits are disposed in partial overlapping relation.

25 19. The intervertebral prosthesis according to claim 18 wherein each support surface has an opening in communication with the inner cavity.

-15-

20. The intervertebral prosthesis according to claim 16 wherein the support surfaces each have an opening therein in communication with the interior cavity.

5

21. The intervertebral prosthesis according to claim 20 including first and second end caps releasably mounted to respective first and second support surfaces.

22. An intervertebral prosthesis, comprising a disc member
10 dimensioned for insertion within an intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom, the disc member defining a longitudinal axis and a radial axis transverse to the longitudinal axis, the disc member including an exterior wall portion having a plurality of slits that follow a multi-directional path, at least portions of the multi-directional path having a longitudinal
15 component, the adjacent slits being disposed in a radial relation with respect to the longitudinal axis, the slits dimensioned to extend sufficiently within the exterior wall portion whereby upon insertion of the disc member within the intervertebral space forces exerted on the disc member are transferred along the exterior wall portion.

20 23. An intervertebral prosthesis, comprising a disc member dimensioned for insertion within an intervertebral space between adjacent vertebrae to replace at least a portion of an intervertebral disc removed therefrom, the disc member having sufficient rigidity to support the adjacent vertebrae in spaced relation, and defining a longitudinal axis, the disc member including an exterior wall portion and an
25 inner cavity, the exterior wall portion including at least one slit defined therein.

24. An intervertebral prosthesis according to claim 23 wherein the at least one slit extends from an outer surface of the exterior wall portion to an inner surface of the exterior wall portion in communication with the inner cavity.

-16-

25. An intervertebral prosthesis according to claim 24 wherein the at least one slit has a longitudinal component of direction and a lateral component of direction.

5

26. An intervertebral prosthesis according to claim 25, wherein the at least one slit is helical.

10

27. An intervertebral prosthesis according to claim 26 wherein the body member includes a plurality of slits.

28. An intervertebral prosthesis according to claim 27 wherein adjacent slits are disposed in at least partial overlapping relation with respect to the longitudinal axis.

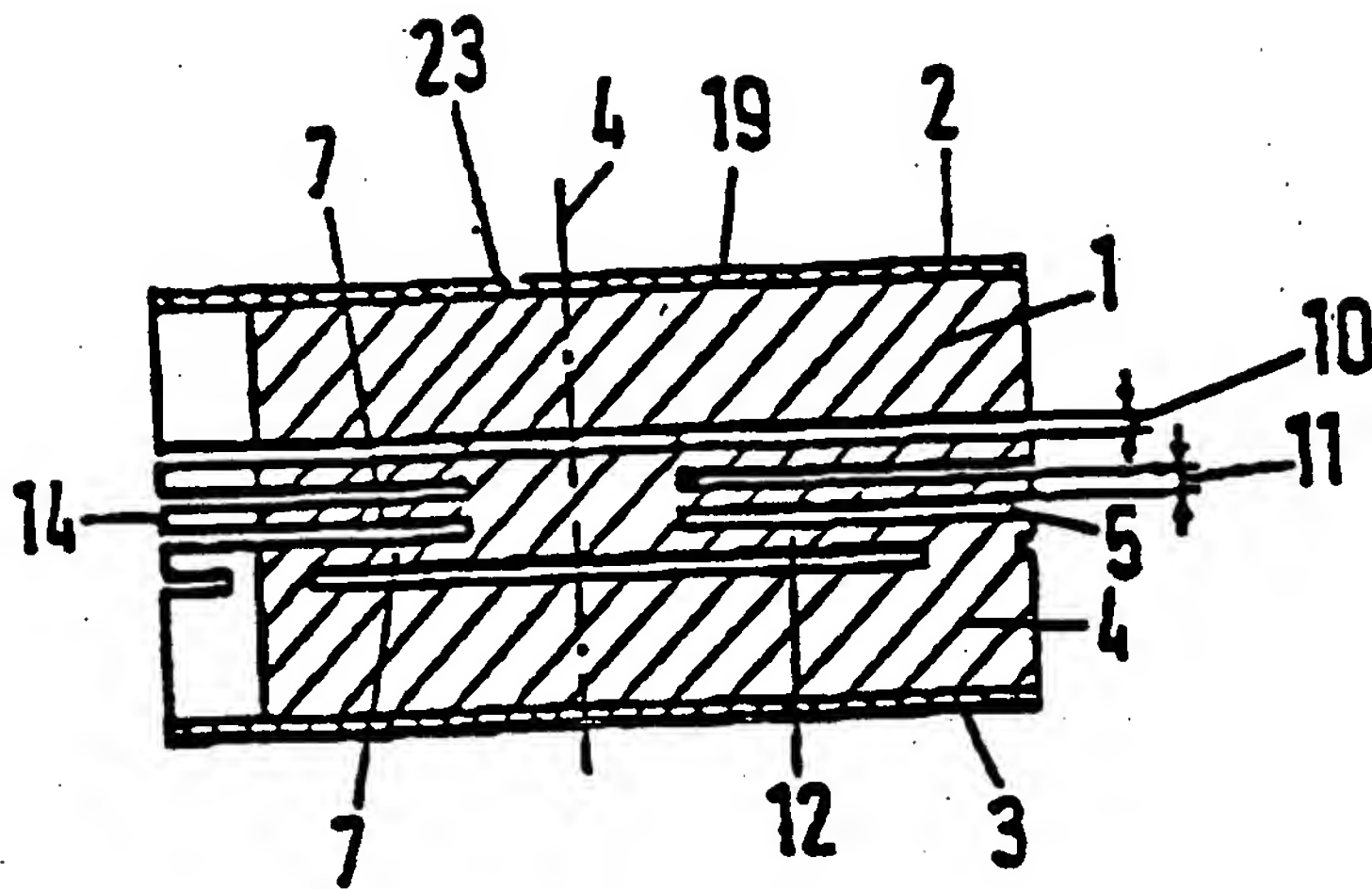


Fig.2
(PRIOR ART)

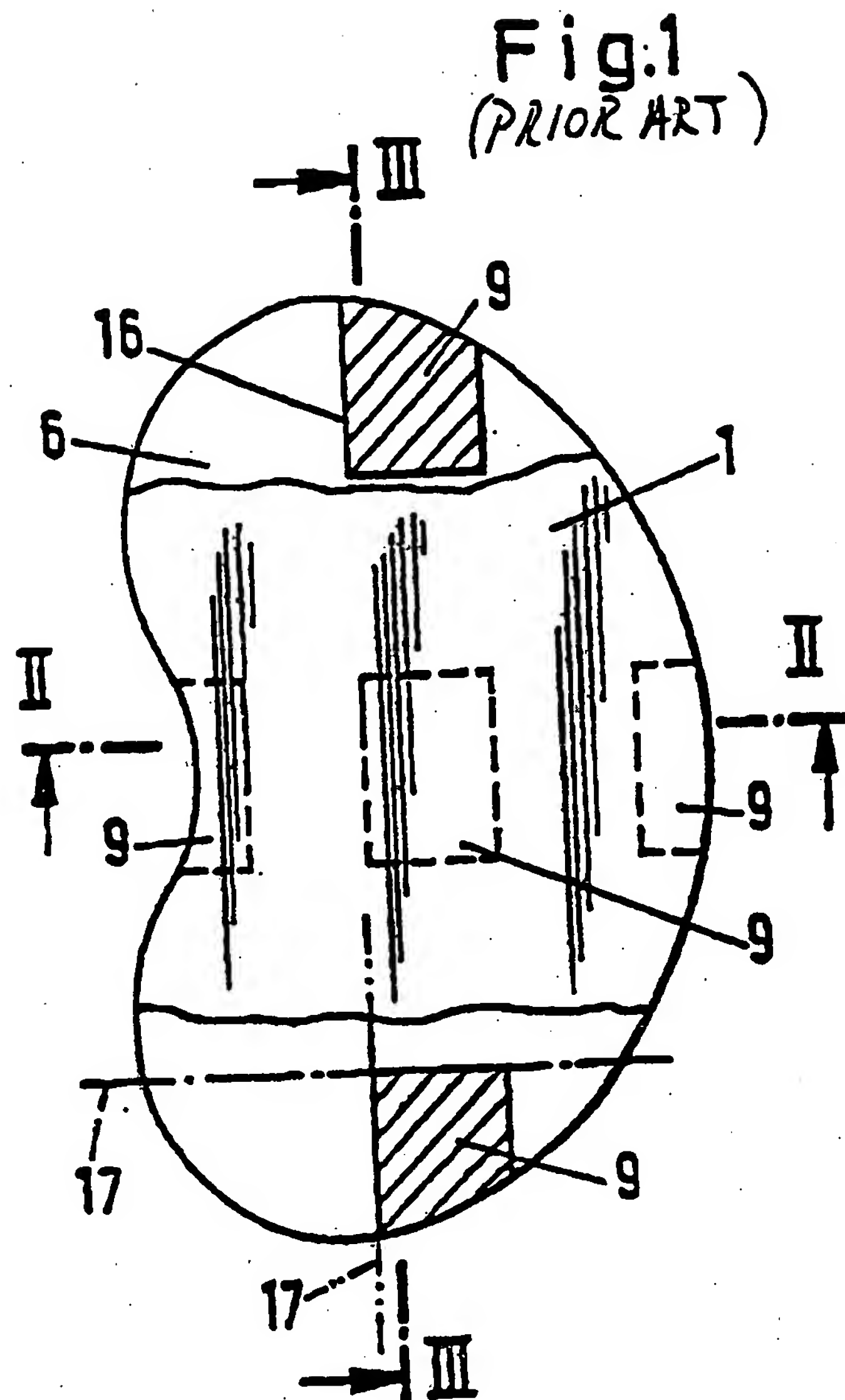
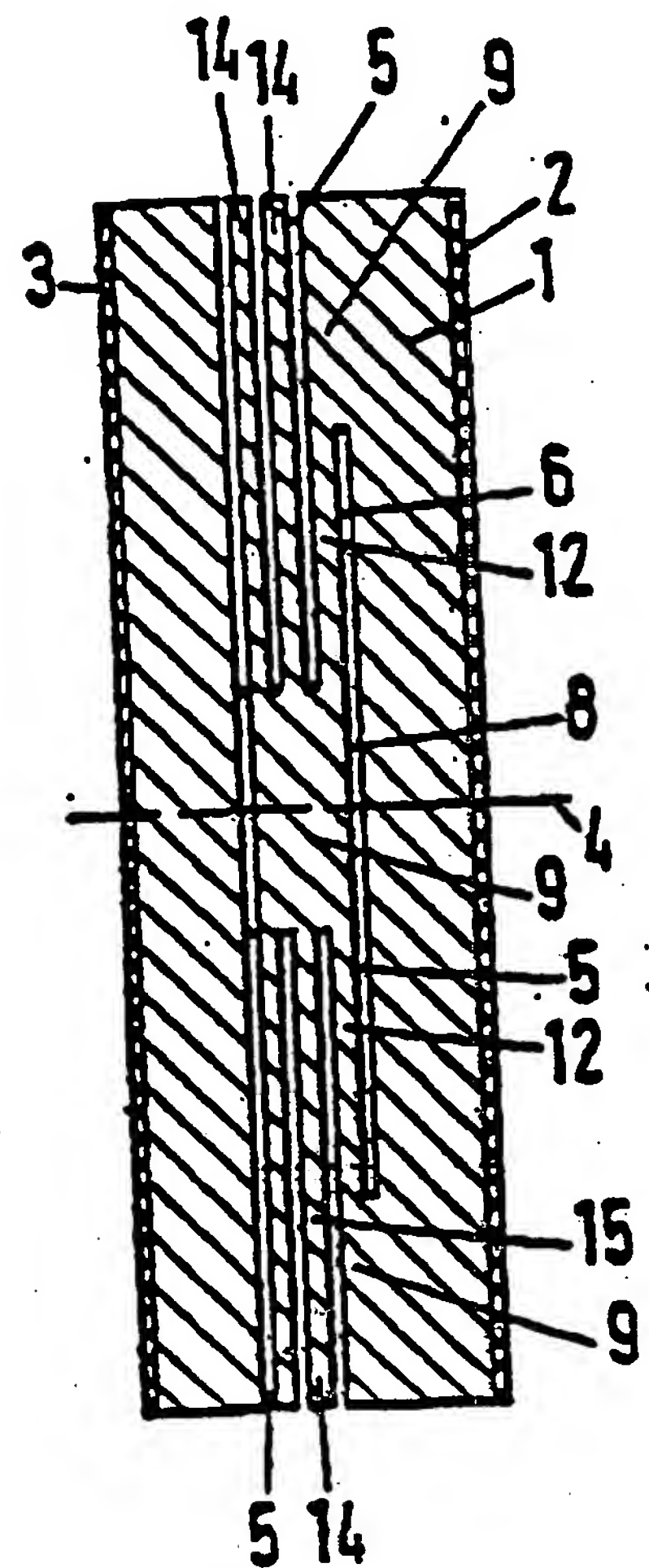
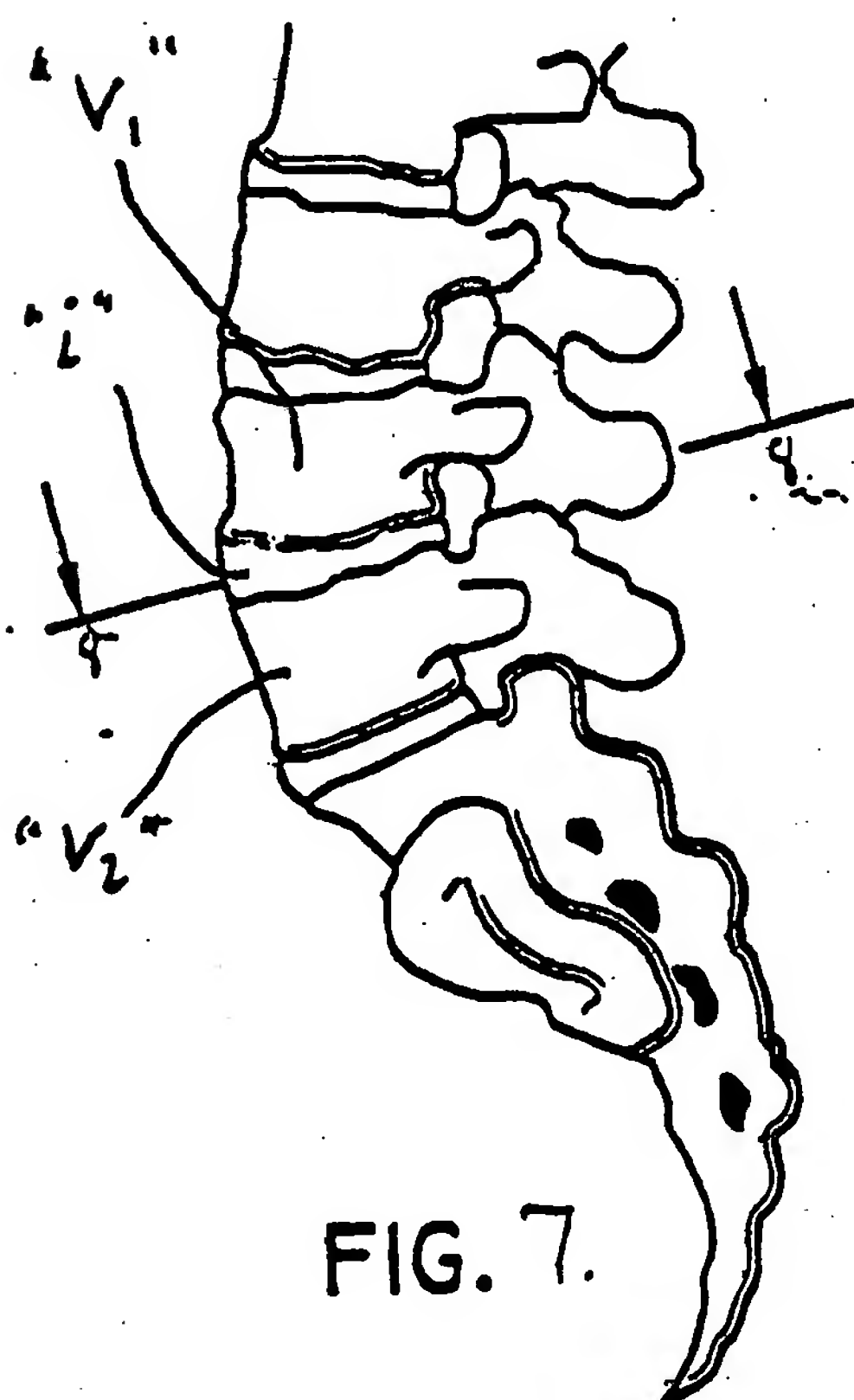
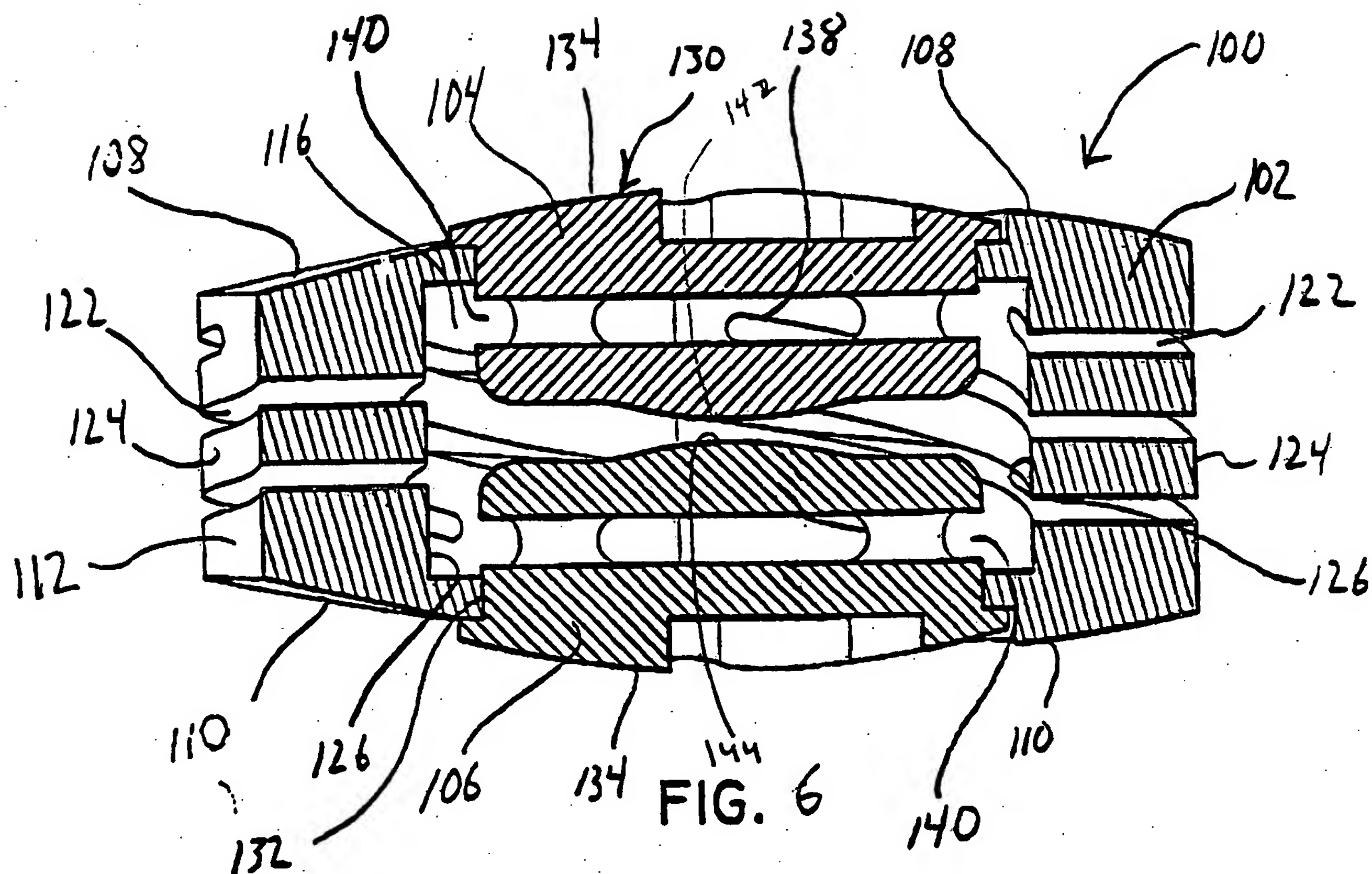


Fig.3
(PRIOR ART)





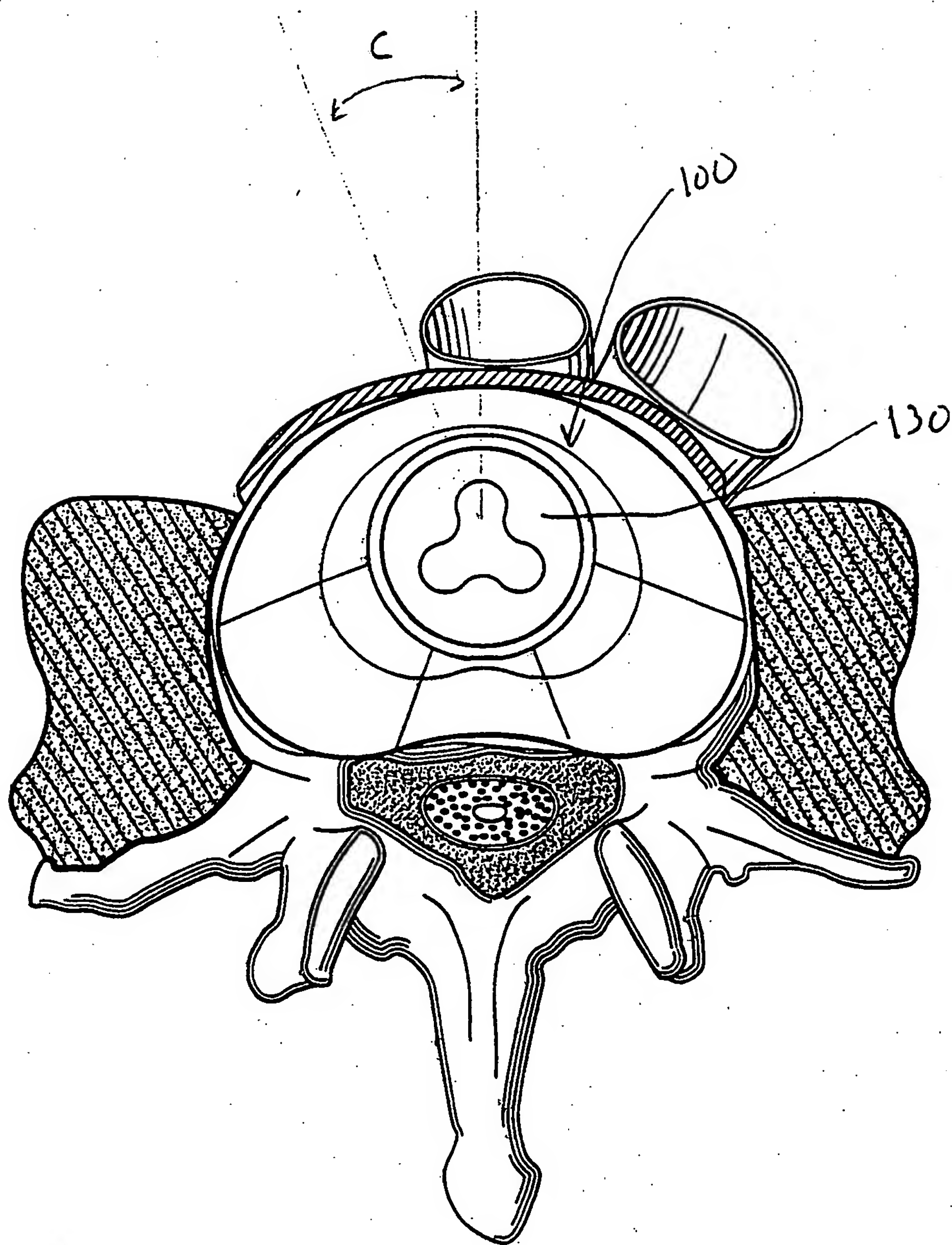
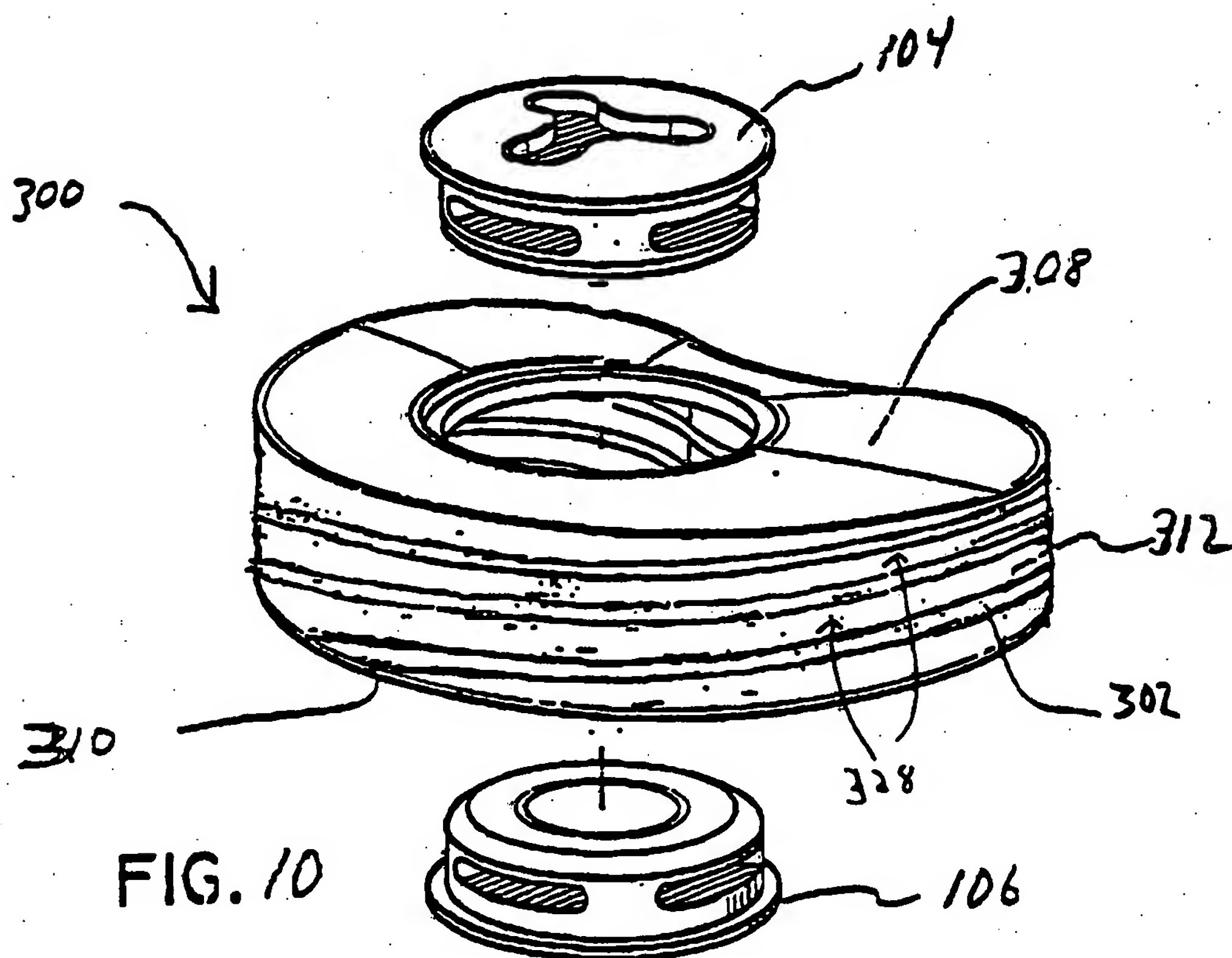
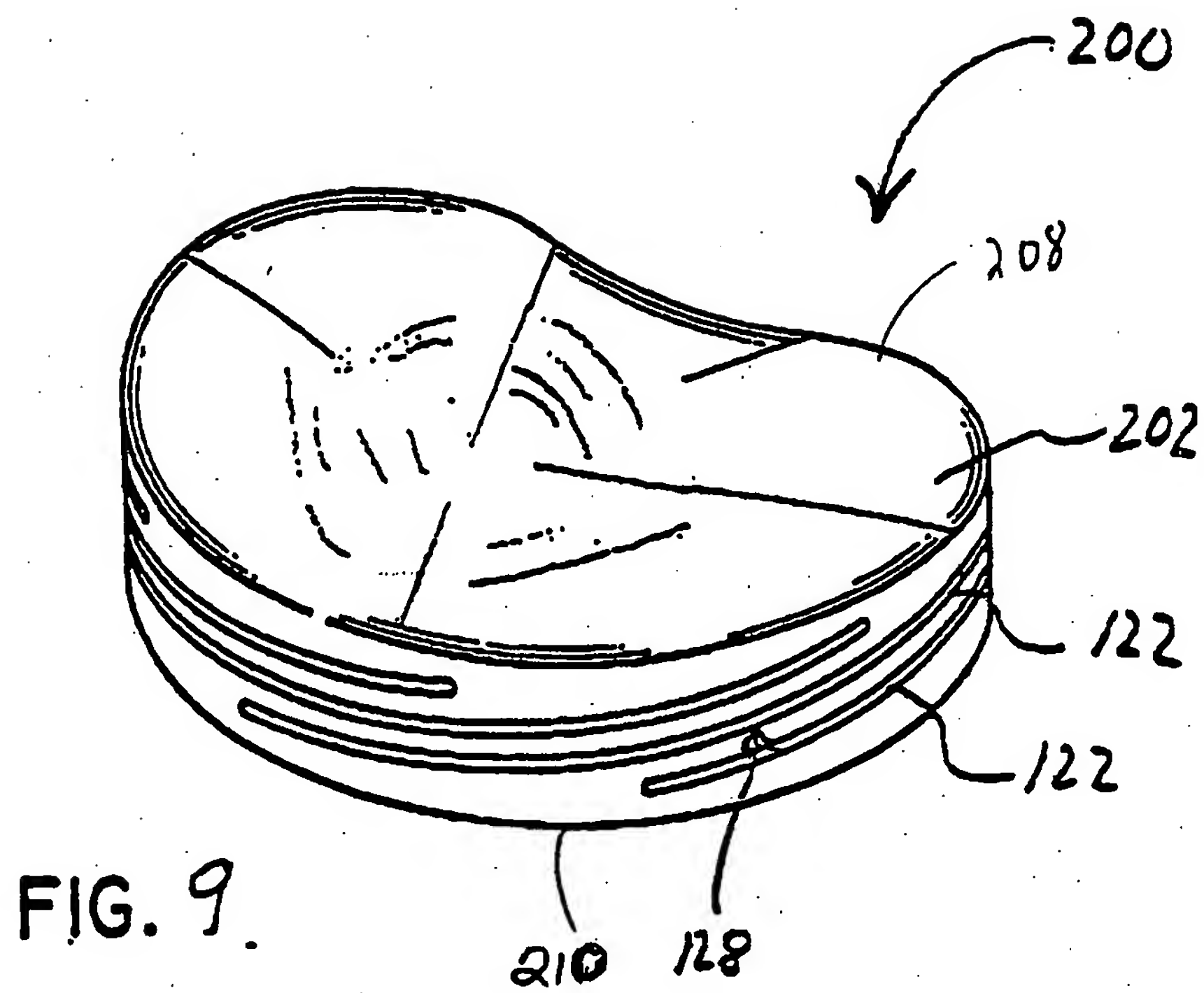


FIG. 8



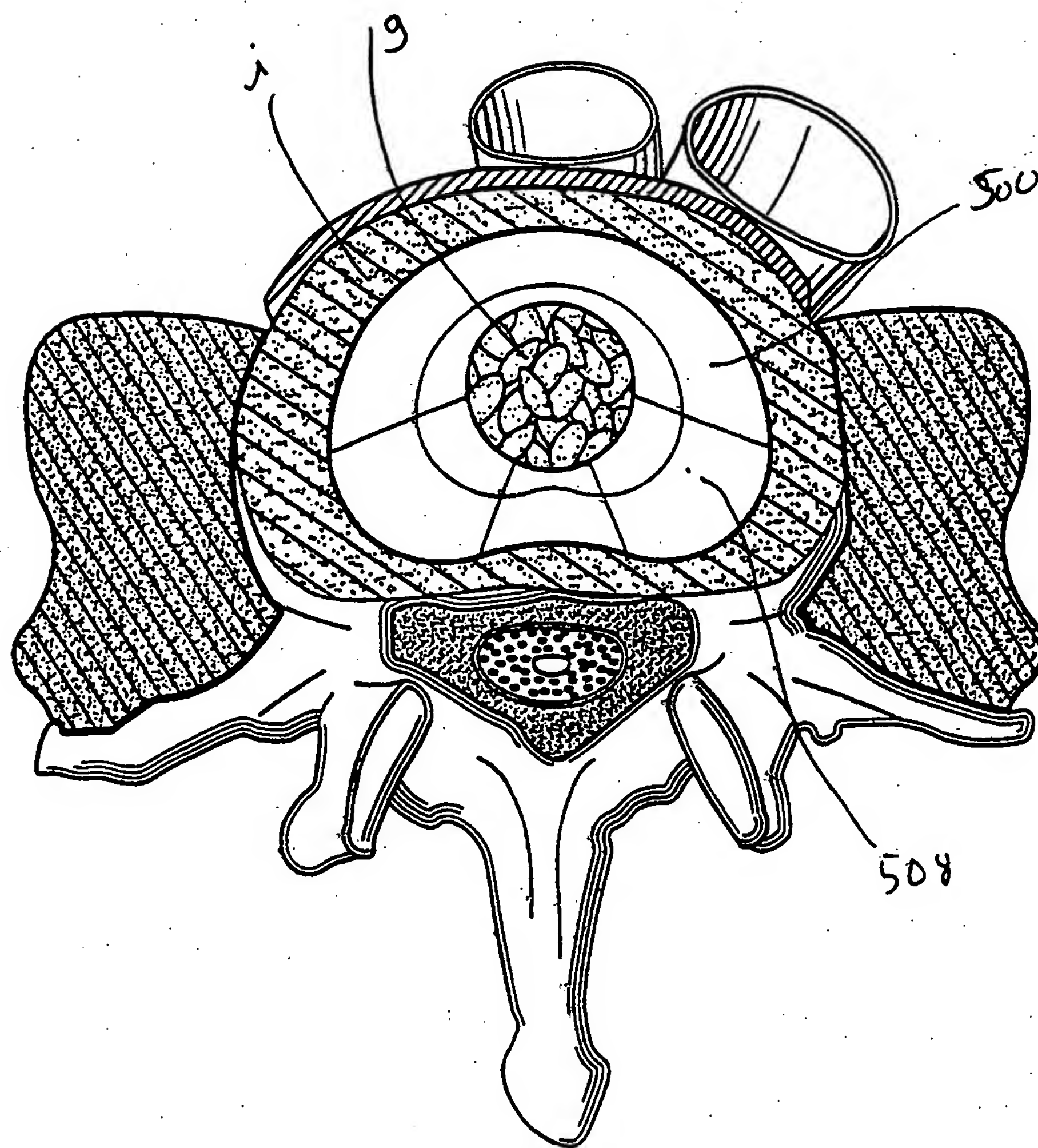


FIG. 11A

